Complete Summary

GUIDELINE TITLE

Palpable breast masses.

BIBLIOGRAPHIC SOURCE(S)

Parikh JR, Evans WP, Bassett L, Berg WA, D/Orsi C, Farria DM, Herman CR, Kaplan SS, Liberman L, Mendelson E, Edge SB, Expert Panel on Women's Imaging - Breast. Palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 4 p. [30 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Radiology (ACR), Expert Panel on Women's Imaging-Breast Work Group. Appropriate imaging work-up of palpable breast masses. Reston (VA): American College of Radiology (ACR); 2003. 4 p. (ACR appropriateness criteria).

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Palpable breast mass
- Breast cancer

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Obstetrics and Gynecology
Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for patients with palpable breast masses

TARGET POPULATION

Women with palpable breast masses

INTERVENTIONS AND PRACTICES CONSIDERED

1. X-ray
    - Diagnostic mammography, bilateral
    - Supplemental mammographic views
2. Ultrasound (US), breast, unilateral
3. Magnetic resonance imaging (MRI), breast

Note: MRI is not indicated in the initial evaluation of a patient with a palpable breast mass.

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in the evaluation of a palpable breast mass

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the most to the least appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Task Force on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Palpable Breast Masses

Variant 1: Woman 30 years of age or older.

Radiologic Procedure	Appropriateness Rating	Comments
X-ray, diagnostic mammography, bilateral	9	CC, MLO view of each breast Marker on mass.
X-ray, supplemental mammographic views	8	
US, breast, unilateral	8	
MRI, breast	2	MRI is not indicated in the *initial* evaluation of a patient with a palpable breast mass.

Radiologic Procedure	Appropriateness Rating	Comments
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 2: Woman younger than 30 years of age.

Radiologic Procedure	Appropriateness Rating	Comments
US, breast, unilateral	9	
X-ray, diagnostic mammography, bilateral (if US shows the following):		
US is suspicious or highly suggestive of malignancy	9	Bilateral diagnostic examination
US is equivocal or negative for findings	8	Diagnostic mammogram tailored to clinical situation
US shows benign or probably benign findings	2	
MRI, breast	2	MRI is not indicated in the *initial* evaluation of a patient with a palpable breast mass.
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Breast cancer is the most common female malignancy and the second leading cause of cancer deaths in the United States. The American Cancer Society estimates that 212,920 new cases of invasive breast cancer and 61,980 new cases of in situ breast cancer will be diagnosed in 2006. A breast mass will be one of the most frequent surgical indications. A palpable breast mass may become evident during breast self-examination (BSE), clinical breast examination (CBE), or retrospectively following screening mammography.

Determining if a mass is present by physical examination can be difficult, as all breasts have variable combinations of glandular tissue, fibrosis, and fat. True masses are generally asymmetrical in relation to the other breast, distinct from

the surrounding tissues, and three-dimensional. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Benign lesions typically have discrete, well-defined margins and are mobile. Cysts cannot reliably be distinguished from solid breast masses by palpation. In one study, only 58% of 66 palpable cysts were correctly identified by physical examination. Significant disagreement among experienced examiners may occur. In another study, four surgeons performed physical examination independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant.

Because many breast masses may not exhibit distinctive physical findings, an imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions. Unfortunately not all palpable breast masses will be visualized with conventional imaging techniques. In the Breast Cancer Detection Demonstration Project (BCDDP) begun in the 1970s, 9% of the cancers were found by CBE alone. With improvement in imaging methods since the BCDDP, this percentage should be considerably less. Nevertheless a negative imaging evaluation should never overrule a strongly suspicious finding on physical examination or vice versa. Any highly suspicious breast mass detected by imaging or palpation should be biopsied unless there are exceptional clinical circumstances such as patient comorbid factors.

Several imaging techniques are commonly used in the evaluation of palpable breast masses. Screening mammography is most useful for early detection of nonpalpable breast lesions. The examination is performed on women thought to be asymptomatic and usually consists of craniocaudal and mediolateral oblique views of each breast. A mass found with screening mammography may become perceptible by palpation after its location has been identified radiographically. Following detection of a clinical or mammographic mass, diagnostic mammography may be performed. A small metal marker is placed on the skin over the mass to identify its location. Supplemental mammographic views may be needed to clarify the features, location, or reality of a mammographic lesion. These views have been discussed extensively and include spot compression, spot compression/magnification, magnification, exaggerated craniocaudal to the medial or lateral side, tangential, change of angle, cleavage, cleopatra, and 90-degree lateral views. Any creative nonstandard view may be used to image a lesion or move it closer to the film. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Ultrasound (US) was initially used only to differentiate cystic from solid lesions. Many palpable masses not visualized mammographically are cysts and can be diagnosed sonographically. With the development of 7.5-10 MHz linear array transducers with excellent near-field resolution, the role of US has expanded to include characterization of the shape, margins, and internal matrix of masses and guidance for needle localization, aspiration, and biopsy. US is also highly accurate in identifying palpable malignant breast masses, although no one exam alone should be used to exclude malignancy.

Fine-needle aspiration/biopsy (FNAB) is used to remove fluid from a cyst and cellular material from a solid mass. Some physicians suggest FNAB as the first

means of evaluation following physical examination, and patients with a palpable mass referred for imaging evaluation may have already undergone FNAB.

Stereotactic (x-ray) or US guidance may be used for FNAB or core biopsy if the mass is vaguely palpable, small, deep, mobile, or multiple, or attempts using palpation to biopsy the mass have been unsuccessful.

The use of multiple modalities in the diagnosis of palpable masses has been advocated as a measure to increase the true positive rate. In one study comparing physical examinations, mammography, and US, the authors concluded that for palpable masses, physical examination and US formed the optimal preoperative test combination. Mammography was also necessary to detect occult cancer in the contralateral or ipsilateral breast. Diagnostic breast US can improve the specificity of clinically detected abnormalities.

The most common uses of US are characterization of palpable and mammographically-depicted masses and guidance for biopsy procedures. Using strict criteria for benign and malignant features for solid masses seen on US, a high negative predictive value (99.5%) is possible to achieve. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is also very high, over 97%.

Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and follow-up is planned. However, a highly suspicious physical examination should prompt biopsy regardless of the imaging findings.

With respect to a palpable breast mass, other imaging techniques remain investigational. Magnetic resonance imaging (MRI) has emerged as a promising modality for detecting occult breast cancer and for evaluating disease extent in women diagnosed with breast cancer. The sensitivity of the exam is high, but specificity continues to be problematic due to false positives. Although palpable masses can be imaged with MRI, it is generally more cost effective to use mammography and US as the initial imaging examinations. In patients with palpable biopsy-proven breast malignancy in nonfatty tissue, MRI appears to be more sensitive than US or mammography for staging, and MRI appears to be superior to clinical examination, mammography, and US for monitoring response to neoadjuvant therapy.

Exciting new prospects for breast cancer detection using molecular imaging are now being actively investigated. A study comparing positron emission tomography (PET) using an isotope of glucose and single-photon-emission computed tomography (SPECT) indicate that both techniques are comparable in diagnosing breast cancer, with a sensitivity of 79% for PET and 76% for MIBI SPECT. In another study MIBI SPECT modified patient management in 49% of patients after a doubtful or discordant triple test with mammography, US, and FNAB. More work must be done to establish criteria for the use of nuclear medicine for breast cancer diagnosis.

Because of the theoretical increased radiation risk and the low incidence of breast cancer (less than 1%) in women younger than 30 years of age, the imaging evaluation for patients over 30 years of age differs from that performed for

younger patients, according to most investigators. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

In determining the utility of mammography in women younger than 30 years of age, most researchers have retrospectively either studied patients referred for mammography or reviewed the mammographic findings of patients in whom cancer was found. In the first group of studies, as one would expect, there was a predominance of benign masses and nonspecific benign findings, although a few carcinomas were found. Most of the benign lesions were not visualized mammographically, and US was suggested as the initial imaging modality. If US demonstrates a suspicious finding, then bilateral mammography is recommended to evaluate for additional ipsilateral and contralateral lesions. If US is negative, then mammography is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically. As with women 30 years of age and older, most investigators agree that if physical examination is highly suspicious and mammography is negative, tissue sampling with FNAB, core biopsy, or surgical biopsy is warranted. In symptomatic young women subsequently proven to have breast cancer, mammography was abnormal preoperatively in 86% to 90%, of them, suggesting it is of substantial value in the diagnosis of malignancy.

Abbreviations

- CC, craniocaudal
- MLO, mediolateral oblique
- MRI, magnetic resonance imaging
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for the evaluation of a palpable breast mass

POTENTIAL HARMS

Specificity of magnetic resonance imaging (MRI) continues to be problematic due to false positive results.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Task Force on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other coexistent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the United States Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Parikh JR, Evans WP, Bassett L, Berg WA, D/Orsi C, Farria DM, Herman CR, Kaplan SS, Liberman L, Mendelson E, Edge SB, Expert Panel on Women's Imaging - Breast. Palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 4 p. [30 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Sep (revised 2006)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging - Breast

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Jay R. Parikh, MD; W. Phil Evans, MD; Lawrence Bassett, MD; Wendie A. Berg, MD, PhD; Carl D'Orsi, MD; Dione M. Farria, MD, MPH; Cheryl R. Herman, MD; Stuart S. Kaplan, MD; Laura Liberman, MD; Ellen Mendelson, MD; Stephen B. Edge, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 25, 1999. The information was verified by the guideline developer on September 9, 1999. The NGC summary was updated on November 12, 2004. The information was verified by the guideline developer on December 21, 2004. This NGC summary was updated by ECRI Institute on May 17, 2007.

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